C-RAD

K063839

510(k) SUMMARY

FEB 8 2007

Owner

C-RAD Positioning AB
Kungsängsvägen 29
753 23 Uppsala
Phone no: +46 18 666930
Fax no: +46 18 126930

Contact person

Bengt-Eric Rösth
Chief Executive Officer
Phone no: +46 18 666933

Date of preparation

December 12, 2006

Trade name of device

Positioner

Common name

Radiotherapy positioning system

Classification name

Medical charged-particle radiation therapy system
Regulation: 21 CFR 892.5050

Predicate marketed devices

AlignRT (K052682) – Vision RT Ltd.

Device description

The system consists of a laser-camera unit (LS-100) mounted in the ceiling, and a Windows based application (cPosition) running on a standard PC.

The system is non-invasive and uses visible laser light (635nm) to project lines on the patient. The laser-camera scans a 3D surface by projecting a series of laser lines which are recorded by the camera. From each camera recording a 3D contour of the measured object is calculated using triangulation technique and by adding the contours a full 3D surface image is achieved.

The PC software compares the scanned image with a reference image and calculates the adjustments required in order to match the two images.

Intended use

The Positioner system is intended for use in radiation therapy clinics to accurately position patients for radiation therapy in a reproducible way. The system provides information about a patient's position and the adjustments required in order to position the patient as a close as possible to a reference setup.

The system shall only be used by hospital personnel, qualified to work in radiation therapy or diagnostics departments.

Technological comparison

The Positioner system is substantial equivalent to the predicate devices in terms of their intended use and technological characteristics. There are differences between the Positioner system and predicate devices in terms of their principles of operation, materials, performance, human factors and energy delivered by the system. However, performance data has been submitted to show that Positioner achieves its intended use and that these technological differences raise no new efficacy or safety concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Bengt-Eric Rösth
CEO
C-RAD Positioning AB
Kungsängsvägen 29
Uppsala 75323
SWEDEN

FEB 8 2007

Re: K063839
Trade/Device Name: Positioner
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: December 20, 2006
Received: December 26, 2006

Dear Mr. Rösth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

C-RAD

INDICATIONS FOR USE

510(k) Number: K063839

Device Name: Positioner

Indications for use:

The Positioner system is intended for use in radiation therapy clinics to accurately position patients in a reproducible way, prior to treatment. The system provides information about a patient's position and the adjustments required in order to position the patient as close as possible to a reference setup.

The system shall only be used by hospital personnel, qualified to work in radiation therapy or diagnostics departments.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063839